UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte JOHN E. SIMS

Appeal No. 2005-1799
Application No. 09/612,921

HEARD: October 4, 2005

Before ELLIS, ADAMS, and GREEN, Administrative Patent Judges.

ADAMS, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on the appeal under 35 U.S.C. § 134 from the examiner's final rejection of claims 58-62 and 65-67, which are all the claims pending in the application.

Claims 59 and 60 are illustrative of the subject matter on appeal and are reproduced below:

59. An isolated nucleic acid molecule comprising the nucleic acid sequence of SEQ ID NO:3.

60. An isolated nucleic acid molecule comprising at least 30 contiguous nucleotides of the nucleic acid sequence of SEQ ID NO:3.

The references relied upon by the examiner are:

Bork et al. (Bork), "Sequences and topology, Deriving biological knowledge from genomic sequences," Current Opinion in Structural Biology, Vol. 8, pp. 331-332 (1998)

Skolnick et al. (Skolnick), "From genes to protein structure and function: novel applications of computational approaches in the genomic era," TibTech, Vol. 18, pp. 34-39 (2000)

GROUNDS OF REJECTION

Claims 58-62 and 65-67 stand rejected under 35 U.S.C. § 101 as lacking utility and § 112, first paragraph, for lack of enablement based on the finding of lack of utility.

Claims 60, 61 and 65-67 stand rejected under 35 U.S.C. § 112, first paragraph, as the specification fails to provide an adequate written description of the claimed invention.

We reverse.

DISCUSSION

Utility:

The examiner rejected all of the claims as lacking patentable utility.[1] Initially, the examiner recognizes (Answer, page 3), "[t]he instant application has provided a description of an isolated DNA encoding a protein and the protein encoded thereby." However, according to the examiner finds (id.), "[t]he instant

[1] The examiner rejected the claims under both 35 U.S.C. § 101 and 35 U.S.C. § 112, first paragraph. However the rejection for nonenablement was presented simply as a corollary of the finding of lack of utility. See Answer, page 6. Therefore, although we discuss only the § 101 rejection, our conclusion also applies to the rejection under the enablement provision of 35 U.S.C. § 112, first paragraph.

application does not disclose a specific biological role for this protein or its significance to a particular disease, disorder or physiological process, which one would wish to manipulate for a desired clinical effect." The examiner then focuses on the biological activity of the protein (IL-1 delta), which is encoded by the nucleic acid of SEQ ID NO. 3, concluding (Answer, page 5),

> [b]ased on the information provided in the instant specification, as filed, one skilled in the art would reasonably conclude that the instant IL-1 delta probably belongs to [the] IL-1 group of cytokines or at least is evolutionary related to the group. However, the artisan [of ordinary skill in the art] would have to perform [a] significant amount of further research to determine which function is attributed to the instant novel IL-1 delta polypeptide.

Accordingly, the examiner concludes (id.), "[i]n the absence of knowledge of the biological significance of this specific IL-1 delta protein or encoding nucleic acid molecule, there is no immediately obvious patentable use for the claimed IL-1 delta nucleic acids."

For clarity, we begin by noting that no claim on appeal is drawn to a protein, peptide, or polypeptide. To the contrary, all claims before us are drawn to nucleic acids that are structurally the same as or share some degree of similarity to SEQ ID NO:3. Therefore, the question before us is whether the claimed nucleic acid has utility. According to appellant's specification (page 37),

> [h]uman IL-1 delta gene maps to chromosome 2q11-12. All or a portion of the nucleic acids of SEQ ID NO:3, including oligonucleotides, can be used by those skilled in the art using well-known techniques to identify human chromosome 2, and the specific locus thereof, that contains the DNA of IL-1 delta family members.
>
> ...
>
> [T]he nucleic acid of SEQ ID NO:3, or a fragment thereof, can be used by one skilled in the art using well-known techniques to analyze abnormalities associated with gene mapping to

> chromosome 2. This enables one to distinguish conditions in which this marker is rearranged or deleted.

However, in the examiner's opinion (Answer, page 11), the fact "human IL-1 delta has a specific location on a specific chromosome does not constitute a specific and substantial utility." According to the examiner (Answer, page 12), "the instant specification fails to provide any evidence or sound scientific reasoning to support a conclusion that this instant nucleic acid of SEQ ID NO:3 is associate[d] with a particular disease or condition, including any of the conditions potentially related to abnormalities within human chromosome 2." Upon consideration of the evidence of record, we disagree with the examiner's finding.

According to appellants (Brief, page 11), "[i]n 1984, a paper[2] was published describing a condition associated with rearrangements or deletions of 2q11-12. ... Mu et al. examined a patient with various abnormalities, and found an abnormal proximal long arm of chromosome 2. ... The authors determined that there was a tandem duplication of 2q11.2-q14.2." According to the Sims declaration (paragraph 13),

> Because of the specificity with which SEQ ID NO:3 or a fragment thereof hybridizes to the specific locus on chromosome 2, I conclude that SEQ ID NO:3 or a fragment thereof can be used for in situ hybridization of chromosome spreads to detect the rearrangement described by Mu et al. That is, SEQ ID NO:3 or a fragment thereof can be used to determine the presence of normal chromosome 2 sequences on one of the chromosomes and for detecting the existence of the duplicated region of the abnormal chromosome in the patient described in Mu et al.

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[2] Mu et al. (Mu), "De novo direct tandem duplication of the proximal long arm of chromosome 2: 46,XX,dir sup(2)(q11•2Q14•2)," J. Medical Genetics, Vol. 21, pp. 57-71 (1984).

Based on this evidence, it is our opinion, the detection of abnormalities in the q11.2-q14.2 region of chromosome 2 as described above and disclosed in appellant's specification is a specific and substantial utility. Accordingly, we reverse the rejection of claims 58-62 and 65-67 under 35 U.S.C. § 101 and the enablement provision 35 U.S.C. § 112, first paragraph.

Written Description:

According to the examiner, claims 60, 61, and 65-67 "do not require that the claimed polynucleotides possess any particular biological activity, nor any particular conserved structure, or other disclosed distinguishing feature. Thus, the claims are drawn to a genus of polynucleotides that is defined only by sequence identity." Answer, pages 6-7. In this regard the examiner finds (Answer, page 7), "[t]he specification only describes an isolated nucleic acid having the sequence of SEQ ID NO: 3 and fails to teach or describe any other nucleic acid which lacks the sequence of SEQ ID NO: 3 and has the activities possessed by IL-1 delta [protein] of the instant invention." We disagree.

"A written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula, [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials." University of California v. Eli Lilly and Co., 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997). The claims in Lilly were directed generically to vertebrate or mammalian insulin cDNAs. See id. at 1567, 43 USPQ2d at 1405. The court held that a structural description of a rat cDNA

was not an adequate description of these broader classes of cDNAs, because a "written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula, [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials." Id. (bracketed material in original).

The Lilly court explained that

> a generic statement such as ... 'mammalian insulin cDNA,' without more, is not an adequate written description of the genus because it does not distinguish the claimed genus from others, except by function. It does not specifically define any of the genes that fall within its definition. It does not define any structural features commonly possessed by members of the genus that distinguish them from others. One skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus.

Id. at 1568, 43 USPQ2d at 1406. Finally, the Lilly court set out exemplary ways in which a genus of cDNAs could be described:

> A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus.

Id.

Our appellate reviewing court revisited the issue of describing DNA. See Enzo Biochem, Inc. v. Gen-Probe Inc., 296 F.3d 1316, 63 USPQ2d 1609 (Fed. Cir. 2002). The Enzo court held that a claimed DNA could be described without, necessarily, disclosing its structure. The court adopted the standard that "the written description requirement can be met by 'show[ing] that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics

... i.e., complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics.'" See id. at 1324, 63 USPQ2d at 1613 (emphasis omitted, ellipsis and bracketed material in original).

Post-Lilly, the court has clarified that the representative species need not necessarily be described in terms of their complete chemical structure. See Enzo Biochem, Inc. v. Gen-Probe Inc., 323 F.3d 956, 964, 63 USPQ2d 1609, 1613 (Fed. Cir. 2002) ("[T]he written description requirement can be met by 'show[ing] that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics ... i.e., complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics.'" (emphasis omitted, alterations in original)).

Our appellate review court has also noted that "Eli Lilly did not hold that all functional descriptions of genetic material necessarily fail as a matter of law to meet the written description requirement; rather, the requirement may be satisfied if in the knowledge of the art the disclosed function is sufficiently correlated to a particular, known structure." Amgen, Inc. v. Hoechst Marion Roussel, Inc., 314 F.3d 1313, 1332, 65 USPQ2d 1385, 1398 (Fed. Cir. 2003). As discussed above, according to paragraph 13 of the Sims declaration,

> [b]ecause of the specificity with which SEQ ID NO:3 or a fragment thereof hybridizes to the specific locus on chromosome 2, I conclude that [the polynucleotide having] SEQ ID NO:3 or a fragment thereof can be used ... to determine the presence of

> normal chromosome 2 sequences on one of the chromosomes and for detecting the existence of the duplicated region of the abnormal chromosome in the patient described in Mu et al.

Accordingly, the claimed polynucleotides have a function, despite the examiner's finding that the "biological activity" of the claimed polynucleotide and the polypeptide encoded thereby is not known. As Sims declares (id.), this function is due to the "specificity with which SEQ ID NO:3 or a fragment thereof hybridizes to the specific locus on chromosome 2." Stated differently, the function can be correlated to the sequence or structure of the claimed polynucleotide.

Regarding the structure, we disagree with the examiner that the claimed polynucleotides lack a conserved structure. We will illustrate this point by reference to four of appellant's claims. First, the examiner does not include appellant's claim 59 in this rejection. Claim 59 reads as follows:

> 59. An isolated nucleic acid molecule comprising the nucleic acid sequence of SEQ ID NO:3.

As we understand it, claim 59 reads on an isolated nucleic acid molecule having the sequence of SEQ ID NO:3 together with any additional molecule (e.g., nucleotide(s)) attached to the 3', 5' or both ends of SEQ ID NO:3. There is no evidence on this record that such a nucleic acid molecule would not function as disclosed in the specification or discussed in the Sims declaration. The examiner, however, finds fault with claim 60, which is drawn to a fragment of the polynucleotide set forth in claim 59. Claim 60 reads as follows:

> 60. An isolated nucleic acid molecule comprising at least 30 contiguous nucleotides of the nucleic acid sequence of SEQ ID NO:3.

As we understand it, claim 60 reads on an isolated nucleic acid molecule having at least 30 contiguous nucleotides of the sequence of SEQ ID NO:3 together with any additional molecule (e.g., nucleotide(s)) attached to the 3', 5' or both ends of SEQ ID NO:3.[3] In our opinion, claim 60 shares structural similarity with claim 59 in that it comprises at least 30 contiguous nucleotides of the sequence of SEQ ID NO:3. There is no evidence on this record that such a nucleic acid molecule would not function as disclosed in the specification or discussed in the Sims declaration. Thus, we disagree with the examiner that the specification does not provide an adequate written description for such a claim.

Next we look at appellant's claim 62, which is not included in this ground of rejection. Claim 62 reads as follows:

> 62. An isolated nucleic acid molecule that hybridizes to either strand of a denatured, double-stranded DNA comprising the nucleic acid sequence of SEQ ID NO:3, wherein the hybridization conditions include 50% formamide and 6XSSC, at 42°C with washing conditions of 68°C, 0.2XSSC, 0.1% SDS.

As we understand it, claim 62 is drawn to a nucleic acid molecule of any percent identity, or similarity, to the nucleic acid of SEQ ID NO:3 as long as it hybridizes under the recited conditions to either strand of a denatured, double–stranded DNA that comprises the nucleic acid sequence of SEQ ID NO:3. Like claims 59 and 60 discussed above, there is no evidence on this record that such a nucleic acid molecule would not function as disclosed in the specification or discussed in the Sims declaration. Further, while the examiner does not include claim 62 in

[3] For clarity, we note that claim 61 depends from and further limits claim 60, by requiring that the nucleic acid molecule comprises at least 60 contiguous nucleotides of the nucleic acid sequence of SEQ ID NO:3.

this rejection, the examiner takes issue with claim 65 which depends from and further limits claim 62 to a nucleic acid molecule that is at least 95% identical to the nucleic acid sequence of SEQ ID NO:3.[4] In our opinion, claim 65 shares structural similarity with claim 62 in that the nucleic acid molecule is at least 95% identical to the nucleic acid sequence of SEQ ID NO:3 and must meet all of the hybridization requirements of claim 62. There is no evidence on this record that such a nucleic acid molecule would not function as disclosed in the specification or discussed in the Sims declaration. Thus, we disagree with the examiner that the specification does not provide an adequate written description for such a claim.

For the foregoing reasons we reverse the rejection of claims 60, 61 and 65-67 under the written description provision of 35 U.S.C. § 112, first paragraph.

REVERSED

Joan Ellis
Administrative Patent Judge

Donald E. Adams
Administrative Patent Judge

Lora M. Green
Administrative Patent Judge

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[4] For clarity we note that claims 66 depends from and further limits claim 65 by requiring that the nucleic acid molecule is at least 98% identical to the nucleic acid sequence of SEQ ID NO:3. Similarly, claim 67 depends from and further limits claim 66 by requiring that the nucleic acid molecule is at least 99% identical to the nucleic acid sequence of SEQ ID NO:3.

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